



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0247]

Food and Drug Administration

Transparency Initiative: Increasing Public Access to the Food and Drug Administration's

Compliance and Enforcement Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: As part of the Transparency Initiative, the Food and Drug Administration (FDA) is announcing the availability of a report entitled "Food and Drug Administration Transparency Initiative: Increasing Public Access to FDA's Compliance and Enforcement Data." This report summarizes findings and recommendations from eight FDA working groups established to enhance the transparency and public accessibility of the Agency's compliance and enforcement data.

FOR FURTHER INFORMATION CONTACT: Daniel W. Sigelman, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4254, Silver Spring, MD 20993, 301-796-4706, FAX: 301-847-8616, email: daniel.sigelman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a report entitled "FDA Transparency Initiative: Increasing Public Access to FDA's Compliance and Enforcement Data." FDA is responsible for a broad range of compliance and enforcement activities.

Increasing the transparency of these activities enhances the public's understanding of the Agency's decisions and promotes accountability of the Agency and the regulated industry.

On October 3, 2011, FDA issued a report entitled, "Food and Drug Administration Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency by Promoting Greater Access to the Agency's Compliance and Enforcement Data." The report advanced eight draft proposals for making FDA's publicly available compliance and enforcement data more accessible and user-friendly (available at:

[http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM273145.p](http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM273145.pdf)

[df](http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM273145.pdf)). Following extensive public comment on the report and internal FDA deliberation, the FDA Commissioner adopted all eight draft proposals, committing FDA to exploring numerous avenues for increasing the transparency and public accessibility of its compliance and enforcement data (see 77 FR 5027, February 1, 2012, and

<http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm289638.htm>).

To develop plans for addressing the eight initiatives, FDA established eight working groups with representatives from all of FDA's centers and several of its offices. Each group was asked to draft a report on its initiative and to include recommendations for moving forward. These efforts culminated in the preparation of this report, which summarizes the eight initiatives and the recommendations from the relevant working groups for enhancing the transparency and public accessibility of FDA's compliance and enforcement data.

Dated: April 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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